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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,753	05/07/2007	Shinichi Morishita	4777-71	3393
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DAY PITNEY LLP 7 TIMES SQUARE NEW YORK, NY 10036-7311			EXAMINER RIGGS II, LARRY D	
			ART UNIT 1631	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/593,753	Applicant(s) MORISHITA ET AL.	
	Examiner LARRY D. RIGGS II	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 17-20,22 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16,21,23,24 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10 August 2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-16, 21, 23, 24 and 26 in the reply filed on 09 July 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 17-20, 22 and 25 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09 July 2009.

Status of Claims

Claims 1-26 are currently pending. Claims 17-20, 22 and 25 are withdrawn. Claims 1-16, 21, 23, 24 and 26 are examined on the merits.

Information Disclosure Statement

The information disclosure statements filed 10 August 2009 is acknowledged. The information disclosed therein has been considered except documents of page 2 which have been lined-through and not considered because no date was provided with the corresponding documents. A signed copy of the corresponding 1449 form has been included with this Office action. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of

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determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Drawings

The amended drawings filed on 22 September 2006 are accepted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites acquiring a specific base sequence candidate appearing in a base sequence of an expressed gene, searching a matching base sequence which matches the specific base sequence candidate..."from a set of base sequences which include a union of sets of a union of sets of exon base sequences..." in lines 5-8. The metes and bounds of the limitation are unclear what is extracted "from a set of base sequences". It is unclear if it is the "specific base sequence candidate" or the "matching base sequence". Likewise, it is unclear if the "set of base sequences" includes the "base sequence of an expressed gene" in lines 3-4.

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Claim 1 recites determining whether the specific base sequence candidate is a specific base sequence "based on whether a plurality of matching base sequences are included in the search result by said search step for a specific base sequence" in lines 11-14. The metes and bounds of the limitation is unclear. The limitation "the search result" lacks antecedent basis because there was no result provided in "searching step" of lines 5-10. It is unclear where "a plurality of matching base sequences" originated because the searching step is not reiterated with a plurality of matching base sequences and there was only one "matching base sequence" in the searching step in line 5.

Claims 3 and 4 recite numerous "base sequence" terms through out the claim. The instant claims depend from claim 1 which recites a base sequence of an expressed gene, specific base sequence, exon base sequences, border base sequences and matching base sequences. It is unclear to which "base sequence" the limitation is referring when recited in the instant claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9, 21, 23 and 26 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

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The recent en banc decision regarding *Bilski v. Warsaw* (2008) set forth that a process is patent-eligible if (1) it is tied to a particular machine or apparatus or (2) it transforms a particular article into a different state or thing.

The instant claims 1-9 and 26 are drawn to a method for searching for a specific base sequence. The instant claims are drawn to the abstract process steps of acquiring a specific base sequence candidate, searching a matching base sequence and determining whether the specific base sequence candidate is a specific base sequence based on the search result.

The instant claims do not recite or inherently involve any transformation of an article, nor do they recite any limitation that ties one or more specific steps of the process to any particular machine or apparatus.

Nominal or token recitations will not suffice, E.g. displaying, inputting, obtaining, See *Ex parte Langemyr* (May 28, 2008). Applicants are cautioned against introduction of new matter in an amendment.

Claims 21 and 23, are drawn to a program; a program, per se, like a signal or carrier wave, is not statutory subject matter. See, e.g., *In re Nuijten*, Docket no. 2006-1371 (Fed. Cir. Sept. 20, 2007)(slip. op. at 18) (“A transitory, propagating signal like Nuijten’s is not a process, machine, manufacture, or composition of matter.’ ... Thus, such a signal cannot be patentable subject matter.”).

For these reasons, claims 1-9, 21, 23 and 26 are considered non-statutory subject matter.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 10-16, 21, 23, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levenkova et al. (Bioinformatics, 2004, 20(3), 430-432) (IDS filed 10 August 2009) in view of Sakharkar et al. (Nucleic Acids Research, 2000, 28(1), 191-192).

The instant claims are drawn to a method, apparatus and program for searching for a specific base sequence comprising the steps of acquiring a specific base sequence candidate from a base sequences of an expressed gene, searching for a matching base sequence from a set of base sequences that includes sets of exon base sequences and border base sequences, and determining whether the specific base

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sequence candidate is a specific base sequence based on the finding of a base sequence that matches the specific base sequence candidate.

Regarding claims 1, 9, 10 and 21 and 23, Levenkova et al. shows a target gene sequence is scanned for candidate siRNA sequences, then BLAST searches of candidate siRNA are performed against databases, where a candidate siRNA sequence is considered gene-specific if it matches a Unigene cluster of sequences, (abstract; page 430, right column - page 432, left column, first paragraph; Figure 1). Levenkova provides programs such as BLAST and TOOL, (pages 430 and 432; Figure 1), which are computerized programs/methods, and thus suggest a computerized apparatus and program for performing the method of Levenkova et al.

Levenkova et al. does not show a set of base sequences that includes sets of exon and border base sequences.

Sakharkar et al. provides an exon/intron (ExInt) database that incorporates information on the exon/intron structure of eukaryotic genes, (abstract; page 191, right column, last paragraph).

Regarding claims 2 and 11 Levenkova et al. shows the position of the AUG start codon and start and end positions, used in the identification of sequences within the databases, (page 430, right column; Figure 1). Sakharkar et al. shows attribute information including position of introns within the coding sequence, (page 191, right column, last paragraph).

Regarding claims 3, 12, 24 and 26, Sakharkar et al. provides an exon/intron (ExInt) database that incorporates information on the exon/intron structure of eukaryotic genes, (abstract; page 191, right column, last paragraph).

Levenkova et al. selects targeted regions that border an expressed gene, e.g. nucleotides around an AUG start site, (page 430, right column). Levenkova et al. provides BLAST searches that utilize user-specified parameters, e.g. number of mismatches in alignment, length of the match between the SiRNA and search hits, (page 430, right column, last paragraph), which meets the instant claim limitation of border base sequences indicating the base sequence from which the introns are obtained, is the same length as the specific base sequence candidate.

Regarding claims 4-7 and 13-16, Levenkova et al. uses BLAST searches using parameters for short nearly identical sequences, user-specified number of mismatches in alignment and length of the match between siRNA and hits and filters the results of the search for matching sequences with % similarity, (page 430, right column, last paragraph – page 432, left column, first paragraph; Figure 1).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the gene specific siRNA selector of Levenkova et al. with the Exon/Intron database by Sakharkar et al. because while Levenkova et al. provides expressed sequence tag (EST) database (Figure 1), Sakharkar et al. shows that the ExInt database provides intron/intron organization of eukaryotic genes present in GeneBank and organizes data for easy access and retrieval on a larger scale, (page 191, left column, first paragraph).

Claims 1-8, 10-16, 21, 23, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levenkova et al. (Bioinformatics, 2004, 20(3), 430-432) (IDS filed 10 August 2009) in view of Sakharkar et al. (Nucleic Acids Research, 2000, 28(1), 191-192), as applied to claims 1-7, 10-16, 21, 23, 24 and 26 above, and further in view of Rouillard et al. (Bioinformatics, 2002, 18(3), 486-487) (IDS filed 10 August 2009).

The instant claim 8 depends from claim 1 with the extra limitation that the specific base sequence candidate is a base sequence of oligo-DNA for microarray.

Levenkova et al. and Sakharkar et al. are applied to claims 1-7, 10-16, 21, 23, 24 and 26 above.

Levenkova et al. and Sakharkar et al. do not show base sequences of oligo-DNA microarrays.

Regarding claim 8, Rouillard et al. provides OligoArray, a program that computes oligonucleotide design for microarrays that is gene specific, wherein the sequences may be mRNA sequences, CDS or exon sequences, (page 486, left column, second paragraph – right column).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the gene specific sequence selector of Levenkova et al. and Sakharkar et al. with oligonucleotide design program for microarrays by Rouillard et al. because Rouillard et al. shows that with the increased number of sequenced genomes, the high throughput technology of DNA microarrays will be facilitated by a gene specific sequence design program OligoArray which is able to forward gene specific designed

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sequences to a search program, e.g. BLAST, (page 486, left column, second paragraph).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY D. RIGGS II whose telephone number is (571)270-3062. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/LDR/

Larry Riggs

Examiner, Art Unit 1631

/Marjorie Moran/

Supervisory Patent Examiner, Art Unit 1631